NOV 18 2011

Section 5: 510(k) Summary K110962

This 510(k) summary has been prepared in accordance with 21 CFR 807.87(h) and the 510(k) has been prepared in accordance with 21 CFR 807.92

Submitter

Ambu A/S
Baltorpbakken 13
DK-2750 Ballerup
Denmark
tel.: +45 7225 2000
fax.: +45 7225 2055

Contact Person

Name: Kaja Tengbjerg
Job Title: Regulatory Affairs Professional
Address: Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup
Telephone number: +45 7225 2215
Fax number: +45 7225 2055

Date Summary Prepared

March, 2011

Device Trade Name

Ambu® aScope™ 2
Ambu® aScope™ Monitor

Device Common Name

Endoscope for endotracheal intubation

Device Classification

Tracheal Tube
Product Codes: BTR
21 CFR 868.5730
Class II

Legally Marketed devices to which the device is substantially equivalent

Manufacturer	Trade Name	510k number
Ambu A/S	Ambu® aScope™ and Ambu® aScope™ Monitor	K093186

Description of the Device

Ambu aScope System consist of Ambu aScope 2 and Ambu aScope Monitor.

Ambu aScope 2 is for viewing anatomical structures in the upper airways, and as an aid in placement of an endotracheal tube (ETT), an ETT size 6 or larger can be used. A camera at the distal tip of the aScope provides the user with an indication of the placement of the aScope. The manoeuvrable tip allows the user to guide the ETT in the desired direction. Ambu aScope is for single patient use and it is sterile.

The Ambu aScope 2 must be connected to Ambu aScope Monitor. The monitor displays the image and it is reusable.

Ambu aScope 2 has the following physical and performance characteristics:

- Manoeuvrable tip controlled by the clinician
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Topical Anaesthetics can be administered to the patient via a channel, with standard Luer connector
- Oxygen flow can be applied via a channel using a flow connector attached to the Luer connector
- Sterile by Ethylene Oxide sterilisation
- For Single Patient Use

Ambu aScope Monitor has the following physical and performance characteristics:

- Displays the image from Ambu aScope 2 on the screen.
- Can be fixed to e.g. an IV pole.
- By connecting a Video Out Cable to the Ambu aScope Monitor the image can be displayed and/or recorded on an external monitor and/or video recorder.
- Reusable device.

Indications for Use

The Ambu® aScope™ 2 is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an intubating laryngeal mask during non- difficult and difficult intubating procedures or for visualization of the airway during Percutaneous Tracheostomy (PT) procedures. The Ambu® aScope™ 2 achieves its purpose by providing the user with a visual confirmation of where the tip of the Ambu® aScope™ 2 is in the human anatomy.

The flexible tip of the Ambu® aScope™ 2 allows the user to guide the ETT in the desired direction. The system is for use in a hospital environment.

The target population is adults/children that have been clinically evaluated for ETT size 6 or larger.

Summary of the technological characteristics in comparison to the predicate devices

Ambu aScope 2 is similar to predicate device:

- They possess a similar Intended Use.
- They both are flexible scopes with a manoeuvrable tip.
- They are single-use devices, which are delivered sterile.
- They both use a LED-light source located at the tip of the scopes
- They possess a CMOS camera located at the distal tip to provide an image
- They have a handle with a control button giving the operator the ability to steer the tip of the scope up and down
- In both devices, an image is provided on a separate monitor

Ambu concludes that the Ambu aScope 2 and Ambu aScope Monitor is substantially equivalent to the predicate device.

Performance Data - Bench

The following data has been submitted in the premarket notification:

Ambu has provided declaration of conformity to the following recognized consensus standards applicable for this type of device:
- ISO 8600-1, ISO 8600-3 and ISO 8600-4 Optics and optical instruments – medical endoscopes and certain accessories.
- ISO 594-1 Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment.

The declaration of conformity is based on test data.
Result: All tests were passed.

Performance test report was submitted to document the following properties of the Ambu aScope 2 (single use):
- Manoeuvrability of tip (accept criteria: 120+/- 10 ° to each side)
- Endurance of the bending section (accept criteria: 50 bends to each side of minimum 90° and 10 bends to each side of 120+/- 10 °)
- Luer channel when used for topical anaesthetics (accept criteria: verification of ability to administer topical anaesthetics through the channel – when 1 ml is injected at least 0.8 ml was expelled in the distal end)
- Luer channel when used for Oxygen (accept criteria: Luer channel is compatible with 10 seconds oxygen flow at 5 bars and 3 L/min. followed by a 3 seconds blocking of working channel at a pressure of 5 bars)
- Temperature at distal end of Ambu aScope (accept criteria: temperature below 41 °C)

Result: All tests were passed.

Performance test report was submitted to document the following properties of the Ambu aScope Monitor (reusable):
- Imaging performance; evaluation of colours, flickering, contrast and brightness, rated on a scale from 1-3, where 1 is best. (accept criteria: rating 1 and max 2 ratings of 2, when 32 scopes are evaluated for all 4 properties (128 evaluations))
- Cleaning endurance of Ambu aScope Monitor (accept criteria: monitor can withstand the prescribed cleaning and disinfection method for 150 times reprocessing)
- Battery capacity of Ambu aScope Monitor (accept criteria: at least 70% battery capacity after 150 times charging and de-charging)

Result: All tests were passed.

Performance test report was submitted to document Shelf life of Ambu aScope 2. Testing was done on finished, sterilized, shipped and aged products:
- Performance test of the Ambu aScope 2. Test according to Final Quality Inspection Procedure of Ambu aScope 2.
  Accept criteria: Product specifications fulfilled
- Sterile packaging integrity of the Ambu aScope 2 pouch.
  Accept criteria: The seal strength must be greater than 0.4 N when tested according to ASTM F88.

Result: All tests were passed

Since the device is in compliance with the listed standards and have passed the listed performance tests, it is concluded that technological characteristics of Ambu aScope 2 and Ambu aScope Monitor is as safe and effective and performs as well as or better than the chosen legally marketed predicate device.

Environmental tests to demonstrate the compliance to the following standards:
Transportation in designated packaging:

- EN 60068-2-27 Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock: 500 repetitive shocks (bump) in each of 6 directions 400 m/s2 (40g)
- EN 60068-2-64 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance: Random vibration 1.6 grms, 10-150Hz, 30 min/axis
- EN 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens: 12 falls from 1.2m height

Tests performed with the product without its packaging:
Bounce

- EN 60608-2-6 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal): Sinus vibration 5Hz, 1grms, 1 hour.

Free fall

- EN 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens:
  Ambu aScope: 2 falls per relevant orientation from 1.2m height to a smooth concrete surface.
  Ambu aScope Monitor: 2 falls per relevant orientation from 0.2m height to a smooth concrete surface.

After each of the above environmental tests, the packaging integrity and the device were inspected, and performance test of the device was performed.
Result: All products and packaging passed the tests.

Based on the above environmental testing Ambu has concluded that Ambu aScope 2 and Ambu aScope Monitor, can withstand the stresses applied to the product during transport and handling prior to the use of the device, and is as safe and effective and performs as well as or better than the chosen legally marketed predicate device.

	Data for compliance to the general requirements for the device were submitted: Biocompatibility tests shows that the device complies with the requirements of ISO 10993-1: - Cytotoxicity (ISO 10993-5) - Sensitization (ISO 10993-10) - Intracutaneous reactivity test (ISO 10993-10) Result: All tests were passed. Tests that verifies the following properties: - Cleaning validation and Liquid Chemical Sterilization and Disinfection Validation of the Ambu aScope Monitor according to AAMI TIR12 and AAMI TIR30, to validate the prescribed method of cleaning and disinfection. - Electro Magnetic Compatibility in compliance with IEC 60601-1-2. - Electrical Safety in compliance with IEC 60601-1 and IEC 60601-2-18. Result: All tests were passed. Since the device passed all the tests to demonstrate compliance to the general requirements for this kind of device, it is concluded that Ambu aScope 2 and Ambu aScope monitor is as safe and effective and performs as well as or better than the chosen legally marketed predicate device.
Performance Data - Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data and comparison to predicate devices it has been concluded that the Ambu aScope 2 and Ambu aScope Monitor has equivalent functionality and intended use as the predicate device. It is concluded that Ambu aScope 2 and Ambu aScope Monitor are as safe and effective and performs as well as or better than the chosen legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Sanjay H. Parikh
Vice President Operations US Agent
Ambu Incorporated
6740 Baymeadow Drive
Glen Burnie, Maryland 21060

NOV 1 8 2011

Re: K110962
Trade/Device Name: Ambu aScope 2
Ambu aScope Monitor
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: November 14, 2011
Received: November 15, 2011

Dear Mr. Parikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known):_____

Device Name: Ambu® aScope™ 2 and Ambu® aScope™ Monitor

Indications for Use:

The Ambu® aScope™ 2 is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an intubating laryngeal mask during non- difficult and difficult intubating procedures or for visualization of the airway during Percutaneous Tracheostomy (PT) procedures.

The Ambu® aScope™ 2 achieves its purpose by providing the user with a visual confirmation of where the tip of the Ambu® aScope™ 2 is in the human anatomy. The flexible tip of the Ambu® aScope™ 2 allows the user to guide the ETT in the desired direction.

The system is for use in a hospital environment. The target population is adults/children that have been clinically evaluated for ETT size 6 or larger.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K110962